UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MOON HAE SUNWOO, ARTHUR A. GERTZMAN
and BRUCE W. STROEVER

Appeal No. 2005-0555
Application No. 09/853,761

ON BRIEF

Before, ELLIS, SCHEINER and MILLS, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the examiner's final rejection of claims 1-5 and 7-37, all the claims pending in the application. Claim 6 has been canceled.

Claims 1 and 34 are illustrative of the subject matter on appeal and read as follows:

1. A sterile flexible bone sheet for use during the in vivo replacement or reformation of preselected portions of an animal skeletal system comprising a continuous integral unitary sheet of demineralized natural bone with a cortical layer and a cancellous layer, said cortical layer interfacing with said cancellous layer through a cortical cancellous section, the thickness of said sheet ranging from 2.0mm to 8.0mm, the sheet being capable of being bent from its original shape to conform to the configuration of a skeletal region to be repaired without damage to the sheet, said sheet being capable of inducing osteogenesis at the skeletal region.

34. A method of making a bone sheet with cortical and cancellous portions comprising:

a). cutting a human bone into substantially tubular portions;

b). cleaning marrow, blood and lipids from said tubular cut human bone;

c). cutting said cleaned tubular bone longitudinally along its length;

d). demineralizing said cut tubular bone rendering the same flexible; and

e). pulling the ends of said bone formed by said longitudinal cut apart to form a bone sheet with cortical and cancellous portions.

The references relied upon by the examiner are:

Boyce et al. (Boyce '939)	5,899,939	May 4, 1999
Boyce et al. (Boyce '187)	6,294,187	Sep. 25, 2001

The claims stand rejected as follows:[1]

I. Claims 1-3, 5-9 [sic, 5, 7-9], 11-14, 27-31, 34, 36 and 37 stand rejected under 35 U.S.C. § 103(a) in view of Boyce '939.

II. Claims 4, 10, 15-26, 32, 33 and 35 stand rejected under 35 U.S.C. § 103(a) in view of Boyce '939 and Boyce '187.

We have carefully considered the respective positions of both the appellants and the examiner and find ourselves in substantial agreement with that of the appellants'. Accordingly, we reverse.

Background

According to the specification, bone replacement and repair are undertaken in many areas of the human skeleton. These areas are said to include "the restructuring of the craniofacial system, bone repair, the introduction of artificial knee and hip joints, and the application of additional features during cosmetic surgery." Specification, p. 1, para. 3. The specification discloses on pages 1-2 that:

> The biological mechanisms underlying the reconstruction and repair varies according to the type of bone implant selected. New bone can be formed by three basic mechanisms: osteogenesis, osteoconduction and osteoinduction. In osteogenic transplantation, viable osteoblasts and osteoclasts are moved from one body location to another where they establish centers of bone formation. Allologous tissue, cancellous bone and marrow grafts provide such viable cells.

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[1] The examiner's Final Office Action, mailed March 14, 2003, in Paper No. 6 includes a double-patenting rejection of claims 1 and 4 over claims 1-10 of U.S. Patent No. 6,326,018. We point out that this rejection has been withdrawn. Answer, p. 15.

> As a generalization, spongy cancellous bone permits rapid and usually complete revascularization.
>
> In the transplantation of large segments of cortical bone or allogenic banked bone, direct osteogenesis does not occur. In these cases, osteoconduction transpires–the dead bone acts as a scaffold for the ingrowth of blood vessels, followed by the resorption of the implant and deposition of new bone. This process is slow, sometimes requiring years to reunite a large segmental defect. As a generalization, cortical bone has high strength and undergoes osteoclastic digestion of the bone and revascularizes through pre-existing anatomical channels, a relatively slow process.
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> Osteoinduction is the phenotypic conversion of connective tissue into bone by an appropriate stimulus. As this concept implies, formation of bone can be induced at even non-skeletal sites. Osteoinduction is the preferred method of providing new bone growth as allografts of this type are typically incorporated into the host bone within several weeks. In contrast, osteoconductive grafts have been found to be non-incorporated as long as one year after implantation.

As indicated by the claims above, the present invention is directed to a bone matrix which is derived from the cortical cancellous bone interface, which is sliced into sheets, demineralized with hyaluronic acid so that the sheets are flexible. The claims further require that the bone sheet comprise a continuous unitary sheet of demineralized bone and have a thickness such that the sheet (i) has sufficient flexibility to allow it to be shaped to conform to the skeletal region which is to be repaired; and (ii) be of sufficient tensile strength to that it [the sheet] can be shaped without damage.

Discussion

I.

The examiner argues that claims 1-3, 5, 7-9, 11-14, 27-31, 34, 36 and 37 would have been obvious to one of ordinary skill in the art in view of the flexible bone sheet taught by Boyce '939. Answer, p. 3. The examiner argues that Boyce '939 discloses a flexible bone sheet "comprising a unitary structure of two or more layers: a demineralized cortical layer and another layer of a different material, where the thickness of the layers range from about 0.5 mm to 20 mm." Id., sentence bridging pp. 3-4. The examiner acknowledges that Boyce '939 does not teach the residual calcium weight percentages (see, e.g., claim 7),[2] but argues that "one could view" said percentages as being "negligible." Id., p. 4, first complete para. The examiner relies on the teachings of Boyce '939 (col. 1, lines 11-17)[3] (and Boyce '187)[4] for support. Id.

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[2] Claim 7 reads as follows:

> 7. A sterile flexible bone sheet according to claim 1 wherein said demineralized sheet has a residual calcium ranging from 3.0% to 8.0% by weight of the demineralized bone mass.

[3] Boyce '939 (col. 1, lines 11-17) discloses:

> More particularly, this invention relates to a bone-derived implant which is made up of two or more layers at least one of which is fully mineralized or partially demineralized cortical bone and, optionally, one or more layers fabricated from some other material.

[4] We point out that the examiner did not rely on Boyce '187 in the statement of the rejection. We caution the examiner that it is well established that "[w]here a reference is relied on to support a rejection, whether or not in a 'minor capacity'," that reference must be positively included in the statement of the rejection." See, In re

In response, the appellants argue that the bone implant disclosed by Boyce '939 differs from the claimed invention in several important aspects. Brief, pp. 5-7. To that end, the appellants argue that Boyce '939 discloses an implant (i) which is "made up of at least two superimposed layers of fully mineralized, or demineralized or partially demineralized cortical bone material adhesively secured or fastened to each other to form a single structure which is then cut into shaped implants"; (ii) which is made from a composite of slices taken from a specific bone and not from a single piece of formed bone; (iii) which is comprised only of cortical bone and does not include the cancellous and cortical cancellous interface portion; and (iv) wherein the layers are held together using biological adhesives and mechanical fasteners. Id. In addition, the appellants argue that Boyce '939 does not teach the method set forth in claims 34-37. Id., p.7. We agree.

It is well established that the examiner has the initial burden under § 103 to establish a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). To that end, it is the examiner's responsibility to show that some objective teaching or suggestion in the applied prior art, or knowledge generally available [in the art] would have led one of ordinary skill in the art to combine the references to arrive at the claimed invention. Pro-Mold & Tool Co. v.

Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970). Accordingly, since it was not included in the statement of the rejection, we have not considered the teachings of Boyce '187 with respect to Rejection I.

Great Lakes Plastics, Inc., 745 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). This the examiner has not done.

First, we find that the examiner's rejection makes no mention as to why the method set forth in claims 34-37 would have been obvious to one of ordinary skill in the art over the teachings of Boyce '939. Accordingly, the rejection with respect to these claims is summarily reversed.

Second, we find that there are three critical differences between the claimed invention and the bone implant disclosed by Boyce '939.

1. We do not find, and the examiner has not pointed out, any teachings in the patent which support his assertion that the bone implant taught therein is flexible. To the contrary, we find that Example 1, col. 6, lines 54-57, states: "The resulting multi-layered unitary structure was cut on a band saw and shaped by grinding and machining with a hand-held motorized shaping tool to provide a shaped bone implant." This difference alone supports our finding that the bone implant taught by Boyce '939 would not have rendered the claimed invention obvious to one of ordinary skill in the art.

2. In addition, we agree with the appellants that Boyce '939 does not teach or suggest the inclusion of a cancellous layer in the bone implant described therein. In this regard, we find the examiner's unsupported argument that the teaching of the inclusion of another layer with the cortical layer taught by the patent "can be a cancellous layer" (Answer, p. 7), to be based solely on hindsight reconstruction of the appellants' specification. In re Gorman, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888

(Fed. Cir. 1991)("It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps"); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985); W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher").

Moreover, we disagree with the examiner's alternative argument that the teachings of Boyce '939 of a bone implant possessing a network of pores, apertures, etc., meets the cancellous layer limitation set forth in the claims. Answer, p. 7. Here, we find that the patent is referring to the texture of the cortical layer following demineralization (see, e.g., the specification, p. 4, lines 11-14), and not to the presence of a cancellous layer. We point out that "cancellous bone" (a.k.a. mesenchymal bone or trabecular bone) is a term of art referring to a specific anatomical structure. That is, in mammals, bones are classified into two types; viz., cortical bone (compact bone) and cancellous bone; the claimed invention requires the presence of both. Thus, we find the examiner's argument that any bone having a network of pores meets the claim limitation of cancellous layer (Answer, pp. 7-8), to be unpersuasive.

3. We find no teachings or suggestions in Boyce '939 of a flexible bone sheet wherein the cortical layer interfaces with the cancellous layer through a cortical cancellous section. The claims require more than a composition comprising a cortical and cancellous layer; they also require that the two layers interface through a cortical cancellous section. Thus, since the claims require that the flexible bone sheet be derived from bone sectioned as described in the specification (see also, claims 34-37) and in Figures 1-5; as opposed to the type of bone sectioning set forth in Figure 1 of Boyce '939, the applied prior art does not teach or suggest the claimed invention.

Accordingly, Rejection I is reversed.

II.

Since the examiner's rejection of claims 4, 10, 15-26, 32, 33 and 35 rests on the premise that the bone implant disclosed in Boyce '939 would have rendered the flexible bone sheet described in independent claim 1 obvious to one of ordinary skill in the art, it reasonably follows we find that Rejection II fails for the reasons set forth above. Accordingly, we reverse.

In view of the foregoing, the decision of the examiner is reversed.

REVERSED

JOAN ELLIS
Administrative Patent Judge)
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Administrative Patent Judge) APPEALS
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